

D. Remarks

The claims are 1-15 and 17-26, with claims 1, 6, 10 and 20 being independent. Claims 1-5, 10-14 and 20-24 have been withdrawn from consideration as being directed to a non-elected invention. Claim 16 has been cancelled without prejudice or disclaimer. Claims 6, 8 and 9 have been amended to resolve formal issues raised by the Examiner. Claim 15 has been amended for clarification. Support for this amendment may be found in cancelled claim 16. Claims 17 and 18 have been amended to resolve formal issues raised by the Examiner and to reflect the cancellation of claim 16. Claim 25 has been amended to reflect the cancellation of claim 16. New claim 26 has been added. Support for this claim may be found, *inter alia*, in Figs. 5A-5C. The specification has been amended to correct typographical, grammatical and syntax errors to conform the text better with proper idiomatic English. Both the errors and the corrections are clear. No new matter has been added.

Applicant has noted that the Examiner crossed out the citation of JP 2001-147231 on the PTO-1449 filed March 17, 2004. The Examiner is requested to consider this document and provide written confirmation of such consideration. Copies of JP 2001-147231 and its English language abstract are available in the IFW of the present case. The concise explanation of relevance for this non-English document is provided in the March 17, 2004 Information Disclosure Statement.

Claims 6-9, 15-19 and 25 stand rejected under 35 U.S.C. § 112, second paragraph.

Applicant has amended claims 6, 8, 9, 15 and 17 to resolve the issues raised

by the Examiner. Therefore, this rejection should be withdrawn.

Claims 6, 7, 15, 16, 18 and 25 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from U.S. Patent No. 5,876,926 (Beecham) in view of U.S. Patent No. 6,187,450 B1 (Staub) and 6,905,827 B2 (Wohlgemuth). Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Beecham, Staub and Wohlgemuth in view of U.S. Patent No. 6,362,004 B1 (Noblett). Claims 17 and 19 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Beecham, Staub and Wohlgemuth in view of U.S. Patent No. 6,021,393 (Honda). The grounds of rejection are respectfully traversed.

Prior to addressing the merits of rejection, Applicant would like to briefly review some of the features and advantages of the presently claimed invention. That invention, in pertinent part, is related to a method for using a DNA microarray to both analyze a specimen collected from a subject and to identify this subject. To achieve this goal, the DNA microarray contains at least two DNA probe groups. The first DNA probe group can be used to identify a subject. The second DNA probe group can be used to test a specimen from the subject. A pattern obtained from the hybridization pattern in the first DNA probe group is analyzed to identify the subject. A pattern obtained from the hybridization pattern in the second DNA probe group is used to generate test information. As a result, according to the present invention, both the identification of the test subject and a test for a disease can be performed using the same sample (specimen) at the same time.

Beecham is directed to a method and an apparatus for obtaining biometric

data from a test subject for identification and testing a sample obtained from the test subject. However, as acknowledged by the Examiner, Beecham fails to disclose or suggest performing these two processes using a single microarray.

Staub is directed to various methods for genetically identifying infants. While one of these methods utilizes a microarray, there is still no disclosure or suggestion of a combined use of the microarray as claimed.

Wohlgemuth is directed to diagnosing and monitoring an autoimmune or chronic inflammatory disease by detecting expression levels of at least one gene. The Examiner alleged that Wohlgemuth teaches that a DNA microarray can include several subsets of probes that can be used for different purposes, and that it would, therefore, have been obvious to combine the identification procedure in Staub with the detection procedure in Beecham on a single chip. Applicant respectfully disagrees with this conclusion and analysis.

Wohlgemuth teaches that several subsets of sequences can be included on a cDNA microarray for diagnostic, prognostic and monitoring purposes. However, Applicant submits that there is no disclosure, which suggests that these different subsets are all analyzed by a hybridization method. The Examiner will note that Wohlgemuth specifically teaches that detection and identification can be performed by different techniques and that these techniques may not involve hybridization (see col. 48, lines 26-30, and col. 23, lines 2-14).

Staub, like Wohlgemuth, teaches various genetic identification methods, not just hybridization. Therefore, the Examiner's specific selection of hybridization in both

Staub and Wohlgemuth appears to have been made in hindsight based on the disclosure in the present application, as nothing in either of these references suggest doing so.

In addition, even if Wohlgemuth teaches hybridization analysis using two separate probe groups, Applicant submits that the probes on the same array in this reference are related to the same disease or condition that is being monitored. Thus, unlike the presently claimed subject identification and specimen analysis, the probe groups in Wohlgemuth are not used for different purposes. Therefore, based on the teachings in Wohlgemuth, a skilled artisan would not look to the probes in Staub, which are used for subject identification, as a possible addition on the same chip to the disease detection array in Beecham.

At most, the disclosure in Wohlgemuth may imply that Beecham could be combined with Staub. However, even if this is so, the fact that references can be combined or modified is not sufficient to establish a *prima facie* case of obviousness. *See* M.P.E.P. 2143.01(III). The prior art must also suggest the desirability of the combination. *See id.* Applicant submit that this suggestion is absent.

The Examiner has alleged in the Office Action that the combination of Beecham and Staub would have allowed for a powerful means of analyzing genetic information. However, if true, using two separate biochips should also lead to such results.

The Examiner further alleged that placing both sets of probes on the same chip would increase the probability of correlation between the test subject and the test results. However, Applicant notes while this advantage is disclosed in the present application, it is not disclosed or suggested in any of the cited references. This further

supports Applicant's position that the Examiner combined Beecham, Staub and Wohlgemuth using the subject application as a blueprint, i.e., used impermissible hindsight.

Noblett and Honda cannot cure the deficiencies of Beecham, Staub and Wohlgemuth. Noblett was cited by the Examiner for a teaching of fiducial marks on a microarray. Honda was cited for a teaching of portable memory cards carried by patients. However, even if these references contain the alleged teachings, they lack the same disclosure that is missing in Beecham, Staub and Wohlgemuth, i.e., performing identification of the test subject and analysis of a specimen using the same DNA microarray.

In conclusion, Applicant respectfully submits that the cited references, whether considered separately or in any combination, fail to disclose or suggest the presently claimed elements. Wherefore, withdrawal of the outstanding rejection and expedient passage to issue are respectfully requested.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicant
Registration No.: 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200